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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,953	02/22/2002	William J. Hennen	2820-4428.2US	6427

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

NOTIFICATION DATE	DELIVERY MODE
02/04/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary	Application No.	Applicant(s)	
	10/081,953	HENNEN ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 18-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 18-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/19/07; 10/3/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response filed November 17, 2007 is acknowledged and entered. Claims 1-16 and 18-23 are pending and under examination.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-16 and 19-23 remain rejected under 35 U.S.C. 102(e) as being anticipated by Dopson (PGPub 2002/0044942A1, "Dopson", published April 18, 2002, with priority to provisional application 60/233,400, filed September 18, 2000).

Applicant's arguments have been carefully. Applicant's arguments are directed to the following:

- Applicant argues that Dopson does not qualify as prior art because Dopson's claim to priority is improper. Specifically, Dopson's disclosure fails to reference provisional application 60/233,400 in the first sentence of the specification or on an application data sheet.
  - In response to Applicant's argument, the oath filed in Dopson's application references and claims priority to the provisional application, 60/233,400. Although Dopson has not complied with the minor informality of referencing the

provisional in the specification or in an ADS, this informality may be corrected at any time.

- Applicant also argues that even if Dopson did qualify as prior art, an affidavit or declaration (37 C.F.R. 1.131) of prior invention would be sufficient to overcome the rejection. Applicant notes that a 1.131 declaration is not appropriate when a rejection is based on a patent or pending application that claims the same patentable invention as defined in C.F.R. 41.203(a). Applicant asserts that the instant invention and the invention claimed in the Dopson application are not the same patentable invention, thus, a 1.131 declaration is sufficient to overcome the rejection. Specifically, Applicant argues that Dopson's most recent claim listing (filed August 13, 2007) is directed to a patentably distinct invention.

- In response to Applicant's argument, the Office has carefully considered the claim sets of the instant invention and the Dopson application. Representative claims from each application are reproduced below for ease of comparison:

10/081,953:

1. (Currently amended) A method for causing a treated animal to elicit a T-cell mediated immune response, comprising administering to the treated animal a quantity of a composition including an extract of an egg obtained from a source animal, said extract comprising transfer factor, generated by said source animal in a T-cell mediated immune response to at least one antigenic agent, treated to purify said transfer factor from other proteins or peptides of the at least one egg having molecular weights of greater than about 8,000 Da, and present in a concentration greater than that present in the egg and in a sufficient quantity to initiate said T-cell mediated immune response in the treated animal.

Dopson 09/954,961, as of August 13, 2007, available from Public PAIR:

Claim 33. (currently amended) A process for producing transfer factor, said process comprising the steps of: immunizing a female bird with a sufficient quantity of at least one selected antigen so that said bird develops immunity to said at least one antigen; after said bird develops immunity to said at least one antigen, collecting fertilized eggs laid by said bird; ~~mixing the fertilized egg whites and fertilized egg yolks with water to produce a suspension; removing cells and cell debris from said suspension to produce a fluid containing at least some of said transfer factor; recovering~~ and treating said fertilized eggs to recover said transfer factor therefrom ~~containing fluid~~.

The claims sets differ because the instant invention is drawn to a method of inducing an immune response by administering transfer factor, and the method of Dopson is a process of producing transfer factor. Since the pending claims do not interfere with Dopson's claims, Applicant may overcome the rejection of record by filing a 1.131 declaration.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(*New Rejection*) Claims 1, 2, 5, 7, 8, 10-13, 16 and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klesius *et al.* (*Poultry Science*, 1984, 63:1333-1337,

"Klesius") in view of Rozzo *et al.* (*Molecular Immunology*, 1992, 29(2):167-182, "Rozzo"). The claims are drawn to a method for inducing a T-cell response in an animal that is administered a composition comprising transfer factor. The transfer factor is purified from eggs generated by a source animal that has been immunized with at least one antigenic agent. The transfer factor is purified from other proteins or peptides having molecular weights greater than out 8 kD. Further, the transfer factor is present in the composition at a concentration greater than that present in the egg.

Klesius demonstrates the transfer of delayed hypersensitivity and protective immunity to chickens when administered transfer factor (abstract). The transfer factor is prepared from splenic leukocytes of chickens immunized with CocciVac®D, which protects against the parasite *Eimeria tenella* (among other *Eimeria* species). The CocciVac®D composition is expected to contain both T-cell and B-cell epitopes, such that a T-cell immune response is generated in the immunized chickens from which the transfer factor is isolated.

Klesius does not disclose the specific method by which the transfer factor is prepared or a molecular weight range of the components in the transfer factor, but references Giambrone *et al.* (*Poultry Science*, 1983, 62:767-771), also silent on the molecular weight range of the components of the transfer factor composition. However, Rozzo characterizes transfer factor and discloses that transfer factor has a low molecular weight, approximately 5 kD (abstract). Rozzo teaches that highly purified transfer factor is desirable in order to study the production and functions of the molecules (abstract). Rozzo's purification method involves the dialysis of spleen cell lysates through membranes with a nominal cut-off value of 6-8 kD (page 171, first column, first paragraph).

Given the molecular weight of transfer factor, it would have been *prima facie* obvious for one of ordinary skill in the art to purify the transfer factor disclosed in Klesius in order to arrive at a highly purified composition of transfer factor. One would have been motivated to purify Klesius' transfer factor composition in order to, as suggested by Rozzo, study its actions more definitively (abstract). By administering highly purified transfer factor in Klesius' method, one would be able to determine more accurately the action of transfer factor as opposed to a combination of actions from interfering molecules present in the composition. Another reason one would have been motivated to purify Klesius' transfer factor is the general practice in the art of purifying molecules of interest. One would have had a reasonable expectation of success that the use of highly purified transfer factor in Klesius' method would have transferred immunity to chickens. The MPEP provides the following guidance on purification of an old product in the context of determining obviousness.

> MPEP 2144.04 VII Purifying an old product
>
> Pure materials are novel *vis-à-vis* less pure or impure materials because there is a difference between pure and impure materials. Therefore, the issue is whether claims to a pure material are unobvious over the prior art. *In re Bergstrom*, 427 F.2d 1394, 166 USPQ 256 (CCPA 1970). Purer forms of known products may be patentable, but the mere purity of a product, by itself, does not render the product unobvious. *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989).
>
> Factors to be considered in determining whether a purified form of an old product is obvious over the prior art include whether the claimed chemical compound or composition has the same utility as closely related materials in the prior art, and whether the prior art suggests the particular form or structure of the claimed material or suitable methods of obtaining that form or structure. *In re Cofer*, 354 F.2d 664, 148 USPQ 268 (CCPA 1966) (Claims to the free-flowing crystalline form of a compound were held unobvious over references disclosing the viscous liquid form of the same compound because the prior art of record did not suggest the claimed compound in crystalline form or how to obtain such crystals.).

See also *Ex parte Stern*, 13 USPQ2d 1379 (Bd. Pat. App. & Inter. 1987) (Claims to interleukin 2 (a protein with a molecular weight of over 12,000) purified to homogeneity were held unpatentable over references which recognized the desirability of purifying interleukin 2 to homogeneity in a view of a reference which taught a method of purifying proteins having molecular weights in excess of 12,000 to homogeneity wherein the prior art method was similar to the method disclosed by appellant for purifying interleukin 2.).

Compare *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989) (Claims were directed to human nerve growth factor b-NGF free from other proteins of human origin, and the specification disclosed making the claimed factor through the use of recombinant DNA technology. The claims were rejected as *prima facie* obvious in view of two references disclosing b-NGF isolated from human placental tissue. The Board applied case law pertinent to product-by-process claims, reasoning that the prior art factor appeared to differ from the claimed factor only in the method of obtaining the factor. The Board held that the burden of persuasion was on appellant to show that the claimed product exhibited unexpected properties compared with that of the prior art. The Board further noted that "no objective evidence has been provided establishing that no method was known to those skilled in this field whereby the claimed material might have been synthesized." 10 USPQ2d at 1926.).

4. (*New Rejection*) Claims 3, 4, 6, 9, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klesius *et al.* (*Poultry Science*, 1984, 63:1333-1337, "Klesius") in view of Rozzo *et al.* (*Molecular Immunology*, 1992, 29(2):167-182, "Rozzo"), as applied to claims 1 and 7 above, and further in view of Kirkpatrick (US Patent 5,840,700). The claims are drawn to embodiments wherein the transfer factor is specific for any one of a variety of antigens listed in claim 14. Also claimed is the administration via the oral, nasal or topical route. Another embodiment is the administration of transfer factor to a mammal.

The combined teachings of Klesius and Rozzo do not teach or suggest transfer factor specific for the antigens listed in claim 14, administration of transfer factor via the routes listed above, the administration of transfer factor after exposure to a pathogen, or the administration of transfer factor derived from eggs to mammals.

Klesius' method of transferring immunity to chickens by administering chicken transfer factor is also applicable to other microbial pathogens in animals (Klesius, page 1337, first column, first full paragraph). Klesius does not specifically mention other pathogens, however, Kirkpatrick discloses the production of transfer factor specific for parasites, bacteria and viruses, such as Epstein-Barr virus and measles (col. 7, lines 60-67 and col. 5, lines 13-17). The transfer factor produced is useful for treating humans and animals. Also disclosed is the transfer of immunity from one species to another by administering transfer factor of one species to another (col. 5, lines 33-36). Kirkpatrick also teaches that transfer factor can be administered intravenously, intramuscularly, subcutaneously or orally (col. 6, lines 56-61). It would have been obvious to modify Klesius' method by producing transfer factor specific for other pathogens, such as those disclosed by Kirkpatrick. One would have been motivated to make this modification in order to transfer immunity against other relevant pathogens besides *E. tenella* in chickens, or other relevant pathogens in other animals. Klesius and Kirkpatrick teach that transfer factor is applicable to multiple pathogens and across species, respectively (Klesius, page 1337, first column, first full paragraph, and Kirkpatrick, col. 5, lines 13-17 and 33-36, for example). Given these teachings, one would have had a reasonable expectation of success that transfer factor produced against other pathogens would have yielded the predictable result of transferring immunity (transfer factor) to that pathogen in the recipient.

With regard to the administration of transfer factor post-exposure to a pathogen, it would have been obvious to modify Klesius' method to administer the transfer factor at that time. One would have been motivated to treat an ongoing infection with the transfer factor (passive immunotherapy) to reduce the pathogenic effects of the active infection. Therefore, the

invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

5. No claim is allowed.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B. Chen/ 1-24-2008
Primary Examiner, TC1600